PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SCB773PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/02749	International filing date *(day/month/year)* 17.03.2003	Priority date *(day/month/year)* 27.03.2002
International Patent Classification (IPC) or both national classification and IPC A23L1/212		
Applicant INDENA S.P.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
02.10.2003	12.07.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Ketterer, M Telephone No. +31 70 340-3645

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/02749

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-7 as originally filed

Claims, Numbers

1-5 received on 15.04.2004 with letter of 14.04.2004

2. With regard to the **language,** all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-5
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-5
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-5
	No:	Claims	

2. Citations and explanations

see separate sheet

V. Reference is made to the following documents:

D1: WO -A- 97/48287
D2: Derwent database WPI, AN=2003-059987[06] & CN-A- 1 358 801

V.1. The subject matter of claims 1-5 seems to fullfill the requirements of the PCT with regard to novelty, inventivity and industrial applicability.

D1 describes a process for the manufacture of tomato products, comprises the steps of: a) pretreating the tomatoes by conventional operations, including crushing; b) subjecting them to a heat treatment; **c) separating the crushed tomatoes into serum and pulp** containing at least 500 ppm; **d) subjecting the pulp to solvent extraction**, in order to extract therefrom an oleoresin containing lycopene; e) separating the spent pulp; and f) separating the lycopene extract from the solvents, whereby to obtain oleoresin containing the lycopene and to recover the solvents.
Current claim 1 defines a process for the **preparation of tomato whole extracts** with lycopene content from 5% to 20% and with reducing sugars content expressed as glucose lower than 1%, comprising the following steps: a) pretreating fresh tomatoes, which comprises washing, then cutting or crushing; **b) heat concentrating of the cut or crushed tomato from step a); c) extracting the concentrate from step b)** with water-saturated ethyl acetate; d) backwashing the extract from step c) with water; e) concentrating the extract to dryness under reduced pressure.
Therefore, the difference between D1 and current claim 1 is that in **D1 only the pulp is subjected to the extraction step, not the serum** (pulp and serum are separated in step c) of the D1-process) instead of the **whole tomato in the claimed process**. There is no such separating step in the claimed process. Claim 1 is therefore novel over D1.
In examples 1 and 2 of D1 **ethyl acetat** is used as extraction solvent for the tomato pulp. In the claimed process there is an extracting step of the the concentrate from step b) with **water-saturated ethyl acetate (step c)**; and then, in step d), backwashing of the extract from step c) with water is carried out and finely, in step e), concentrating the (lycopene comprising) extract to dryness under reduced pressure. Step d) obviously leads to the decrease of the sugar content in the final lycopene concentrate, wich is lower than 1% [expressed as glucose]. Such a backwashing step is not documented in D1, the sugar content in D1's lycopene preparations is obviously higher than in the preparations of current claim 5, which seems also novel over D1.

V.2. The problem underlying the current application can be formulated as 'finding a alternative process for the preparation of tomato extracts with high content in lycopene

and low content in sugar', which is more or less the same underlying D1, considered as the closest prior art.. A skilled person now would not skip the serum/pulp-separation step disclosed in D1 and add a further backwashing step with water after step e) or f) in D1 to further lower the sugar content. To modify the process of D1 additional inventive efforts would be necessary.

Independent claims 1 and 5 are considered being novel and inventive over D1.

The process of D2 lacks the use of **water-saturated ethyl acetate** instead of **ethyl acetate** (as also D1 does), no water back-extraction step is documented, no reference to the sugar content is made. Claims 1-5 are therefore also novel and inventive over D2.

CLAIMS

1) A process for the preparation of tomato whole extracts with lycopene content from 5% to 20% and with reducing sugars content expressed as glucose lower than 1%, comprising the following steps:

a) pretreating fresh tomatoes, which comprises washing, then cutting or crushing;

b) heat concentrating of the cut or crushed tomato from step a);

c) extracting the concentrate from step b) with water-saturated ethyl acetate;

d) backwashing the extract from step c) with water;

e) concentrating the extract to dryness under reduced pressure.

2) A process as claimed in claim 1, wherein the concentration of the extract according to step e) is carried out to a final volume ranging from 0.10 to 0.28% with respect to the starting volume, further comprising the following steps:

f) filtering and drying the lycopene precipitated from the concentrate; and optionally suspending lycopene in ethanol or ethyl acetate, then filtering and washing with ethyl acetate until obtaining the desired purity;

g) adding seed oil to lycopene from step f).

3) A process as claimed in claim 2, wherein the seed oil is tomato seed oil.

4) A process as claimed in claim 2, wherein the seed oil is soybean oil.

5) Tomato whole extracts with lycopene content from 5% to 20% and with content in reducing sugars, expressed as glucose, lower than 1%, obtainable with the process of claim 1.

6) Crystalline lycopene with purity higher than 50% obtainable according to the process of claim 2-f).

7) Crystalline lycopene with purity higher than 90% obtainable according to

the process of claim 2-f).

8) Oleoresins containing lycopene of claim 7) obtainable with the process of any one of claims 2-4.

CLAIMS

1) A process for the preparation of tomato whole extracts with lycopene content from 5% to 20% and with reducing sugars content expressed as glucose lower than 1%, comprising the following steps:

a) pretreating fresh tomatoes, which comprises washing, then cutting or crushing;

b) heat concentrating of the cut or crushed tomato from step a);

c) extracting the concentrate from step b) with water-saturated ethyl acetate;

d) backwashing the extract from step c) with water;

e) concentrating the extract to dryness under reduced pressure.

2) A process as claimed in claim 1, wherein the concentration of the extract according to step e) is carried out to a final volume ranging from 0.10 to 0.28% with respect to the starting volume, further comprising the following steps:

f) filtering and drying the lycopene precipitated from the concentrate; and optionally suspending lycopene in ethanol or ethyl acetate, then filtering and washing with ethyl acetate until obtaining the desired purity;

g) adding seed oil to lycopene from step f).

3) A process as claimed in claim 2, wherein the seed oil is tomato seed oil.

4) A process as claimed in claim 2, wherein the seed oil is soybean oil.

5) Tomato whole extracts with lycopene content from 5% to 20% and with content in reducing sugars, expressed as glucose, lower than 1%, obtainable with the process of claim 1.